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Akihiko Yanaga

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EXAMINER

FLORY, CHRISTOPHER A

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/510,985	Applicant(s) YANAGA, AKIHIKO	
	Examiner CHRISTOPHER A. FLORY	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,5 and 11-17 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,5 and 11-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 15 January 2009 have been fully considered but they are not persuasive. Claim 12 stands rejected under 35 U.S.C. 112, first paragraph. Claims 1, 12 and 13 stand rejected under 35 U.S.C. 102(b) as anticipated by Granzotto'392 or, in the alternative, under 35 U.S.C. 103(a) as obvious over Granzotto'392, or Granzotto'392 in view of Reinhold'823, or Granzotto'392 in view of Marangoni'783. Claims 4, 5 and 11 stand rejected under 35 U.S.C. 102(b) as anticipated by Granzotto'392 or, in the alternative, under 35 U.S.C. 103(a) as obvious over Granzotto'392 in view of Reinhold'823, or still alternatively as obvious over Granzotto'392 in view of Marangoni'783 further in view of Reinhold'823.
2. Regarding Applicant's argument that the limitations of claim 12, namely that the arm portions are integrally formed with the body case can be supported by Figures 1a and 1b, neither Figure 1a or 1b, nor the remainder of the figures, is presented at a perspective to support the Applicant's assertion that there are no intermediate elements between the arm portions 4 and body case 3 that would suggest an integral formation. The lines between the body 3 and arms 4 of the device as seen in Fig. 1a suggest the opposite, as it denotes a clear division between the two. Figure 1b does not remedy this deficiency, since it only shows that arms 4 are perhaps integrally formed with a bottom plate which additionally mimics the shape of top portion 3b. The figures do not preclude the construction that a rectangular top piece is set on top of a T-shaped piece forming the arms. As such, the §112 rejection of claim 12 is considered proper and is

maintained since integral formation or the arms with the body case cannot be upheld solely on the drawings as submitted.

3. In response to Applicant's repetitive argument that Granzotto'392 fails to disclose the switching means starting detection, display and transmission after all the push-down switches are pushed down and maintained for a specific period of, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. As previously pointed out, the term "switching" adds enough structure and function to the phrasing such that 112, 6th paragraph is not considered to be invoked. Regarding claim 17, it is noted that the next to last clause provides significant structural limitation to the means for starting, such that again 112, 6th paragraph is not considered to be invoked.

Applicant further states that the function of the Granzotto'392 stethoscope would perform detection immediately upon extension of the arms, rather than waiting a specific period of time. It is first noted that even immediate activation of the device would read on the language requiring a "specific period of time" since an instant is a measure of time. Additionally, Applicant has not taken into account the previously argued point that Granzotto'392 further discloses that the contact electrodes must also be pressed firmly to the body before any readings will be made, such that detection would not begin immediately upon extension of the arms but only when extension is performed in

conjunction with the pushing down of the electrodes on the body, which could happen immediately but could also happen several seconds, minutes or hours later.

It is additionally noted that the arms of Granzotto'392 can be considered push down in that opening the arms (i.e. pushing them into an open configuration) constitutes the pushdown switch. The claim language nowhere specifically states that the buttons are pushed down relative to the body, merely that they are push down buttons held against the body.

4. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

5. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

6. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that the device is intended for use by the patient himself) are not recited in the

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rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Additionally, the Granzotto'392 device is clearly capable of use by a patient since it is handheld, portable, and has a user-friendly interface.

7. Applicant's arguments against Reinhold'823 and Marangoni'783 are considered moot since it has been shown that Granzotto'392 sufficiently reads on the argued claim limitations.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claim 12 stands rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not recite that the arm portions of the device are integrally formed with the body case, nor is this feature made obvious from the drawings.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 15 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. Claims 15 and 16 recite the limitation "said body portion" on numerous instances. There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

13. Applicant is advised that should claim 1 be found allowable, claim 17 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). The next to last clause of claim 17 lends significant and substantial structural limitations to the means for starting, such that the language is equivalent in scope to claim 1.

Claim Rejections - 35 USC § 102/103

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 1, 12, 13 and 15-17 are rejected under 35 U.S.C. 102(b) as anticipated by Granzotto et al. (US Patent 6,757,392, hereinafter Granzotto'392) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Granzotto'392, or Granzotto'392 in view of Reinhold, Jr. (US Patent 5,339,823, hereinafter referred to as Reinhold'823), or Granzotto'392 in view of Marangoni (US 4,535,783, hereinafter Marangoni'783).

Regarding claims 1 and 17, Granzotto'392 discloses an electrocardiograph (column 1, lines 60-67) comprising a body case (Fig. 1, headpiece 1) which is held on a chest portion of a subject (ABSTRACT; column 3, lines 8-22); a common electrode provided on a back surface of said body case (Fig. 4, fixed electrode 16); a pair of arm portions which extend from said body case (Fig. 4, arms 18); electrodes for detecting electrocardiographic complex which are provided in both end portions of said pair of said arm portions respectively (Fig. 4, electrodes 17; column 2, lines 1-7); a detecting means for detecting electrocardiographic complex based on signals detected by said electrodes (column 4, lines 51-59); a display means for displaying said electrocardiographic means (Fig. 3, LCD 11 displays the electrocardiographic complex and heart rate); a transmitting means for transmitting said electrocardiographic complex (LCD 11 can be considered a transmitting means; likewise, circuitry or wiring between the disclosed memory and display constitutes a transmitting means. Granzotto'392 shows said body case suspended from a neck of said subject by a suspending means (Fig. 1, flexible bows 31; column 2, lines 3-39).

Further regarding the switching means of claims 1 and 17, Granzotto'392 discloses switching contacts at pivot joints 19 for the purpose of connecting electrodes

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17 to the main body electrode only when the arms are in a fully extended position (column 4, lines 7-27), while the unit will otherwise function as a passive auscultatory device. This can clearly be seen as a disclosure of a switching means that would start detection, display and transmission of the electrocardiographic complex to the LCD, where data would only be recorded if the device were placed in contact with the chest portion of the subject. Granzotto'392 further discloses that the arm parts are molded of a flexible plastic and incline at an obtuse angle which changes under pressure on the stethoscope head, and further that such manual pressure on the stethoscope head is necessary to achieve firm contact of the electrodes to detect, display and record the electrocardiographic information (column 4, lines 1-47, emphasis on lines 28-47). This can reasonably be considered a disclosure of push-down switches either in that the arm pivot switching contacts or the electrodes themselves must be pushed down with this manual pressure in order to make contact with all electrodes to the skin in order to detect, display and record the electrocardiographic complex, such that when this push-down pressure is not applied, contact is not made and the ECG complex is not detected.

Alternatively, push-down switches located in the electrode contacts of externally applied ECG and heart rate acquiring electrode devices are well-known in the art (e.g. treadmills, bathroom scales, or other devices where bi-point electrocardiographic data acquisition is desired through a gripping or weight-bearing means) as a simple to manufacture and reliable means of conserving battery or device power by disconnecting the ECG circuit when the user is not applying gripping or weight-bearing pressure on

the device since no useful data could be collected in such a situation. Simultaneous application of pressure to both electrode contacts in these configurations initiates ECG collection, analysis and readout. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Granzotto'392 with push-down switches located in the electrodes to provide Granzotto'392 with the same well-known advantages of conserving device power by only collecting ECG data when pressure is applied to the electrodes to signify a significant connection to a patient for whom collection of ECG data is desired.

Still further in the alternative, Reinhold'823 teaches a device wherein human pressure is applied to engage an array of electrodes with the skin of the chest of an individual to place the electrodes in an operative relation to obtain electrocardiogram data from the individual (abstract; column 2, lines 20-35). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Granzotto'392 with the pressure-activated electrodes and control protocol as taught by Reinhold'823 to provide Granzotto'329 with the same advantage of engaging an electrode array to the chest in an operative relation so as to be able to effectively obtain electrocardiogram data.

Still further in the alternative, Marangoni'783 teaches an electrocardiography recorder in which electrodes (Fig. 1A, electrodes 7 and 8) are disposed over an pressure switch (Fig. 4, switch 21) in such a way that the switch is actuated when the contacts are brought into contact with the skin with a predetermined minimum satisfactory pressure to initiate recording of ECG data, and not record ECG data

otherwise (column 4, lines 19-38). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Granzotto'392 with the press-down electrode switching means as taught by Marangoni'783 to provide Granzotto'392 with the same advantage of recording ECG data only when satisfactory pressure contact between the electrodes and the skin have been made.

Regarding claim 12, arm joints (19) of Granzotto'392 can reasonably be considered integral to the body since they are stored in a closed function inside the body case. Alternatively, Reinhold'823 clearly shows a device with integral arm portions (Fig. 5, where arm portions are considered to contain electrodes V1, V2, V5 and V6) in order to conform to the body and maintain proper electrode alignment under pressure.

Regarding claim 13, Granzotto'392 can reasonably be interpreted as elongated and clearly shows a first and second ends where the arm portions are attached. Alternatively, Reinhold'823 is clearly elongated.

Regarding claims 15 and 16, and further regarding claims 1 and 17, it is noted that Figure 5 of Granzotto'392 clearly shows a t-shaped device with the top arms forming the crossbar and the bottom arm and body forming the vertical base. Alternatively, it would have been an obvious matter of design choice to one of ordinary skill in the art at the time of the invention to modify the system as taught by Granzotto'392 with the t-shaped configuration, because Applicant has not disclosed that said t-shape provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the configuration as taught by Granzotto'392,

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because it provides a means for properly positioning the recording electrodes and since it appears to be an arbitrary design consideration which fails to patentably distinguish the instant application over Granzotto'392 .

16. Claims 4, 5 and 11 stand rejected under 35 U.S.C. 102(b) as anticipated by Granzotto'392 or, in the alternative, under 35 U.S.C. 103(a) as obvious over Granzotto'392 in view of Reinhold'823, or still alternatively as obvious over Granzotto'392 in view of Marangioni'783 further in view of Reinhold'823.

Regarding claims 4 and 5, it is evident from the scope of the disclosure in Granzotto'392 that non-paste electrodes are inherently necessary for proper function of the Granzotto'392 device. It is well known that stethoscopes operate by being placed temporarily on the chest of a subject and are held there by human force rather than adhesive means. Granzotto'392 further discloses that electrodes 17 are moveable (column 4, lines 1-27) and applied through pressure (column 4, lines 45-47) rather than adhesive means.

Alternatively in the same field of endeavor, Reinhold'823 teaches the use of non-adhesive precordial electrodes on an electrocardiograph device in which human pressure is applied to engage the array of six precordial electrodes with the skin of the chest of the individual in an operative relation (ABSTRACT; column 4, lines 54-66). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Granzotto'392 with the non-adhesive electrodes of Reinhold'823 to provide the Granzotto'392 system with the advantage of temporarily

applying the device to a patient in an operative relation with human pressure contact (motivation to combine provided by Reinhold'823 ABSTRACT; column 4, lines 54-66).

Regarding claim 11, the suspending means of Granzotto et al. is considered to be detachable because the bows 31 are made of a rigidly flexible material known in the art which hold the device on the neck of a user while in their resting configuration, but can be manually separated to allow removal of the device from the neck. The suspending means of Granzotto et al. is detachable to said body case because the bows 31 could be physically removed from the chest-piece 2 without altering in any way the function of the electrocardiograph subsystem.

Alternatively in the same field of endeavor, Reinhold'823 teaches an electrocardiograph device employing a lanyard for engagement around the neck of the user (column 5, lines 1-20). It is well known that a lanyard, such as one used on a set of keys or on a personal camera, comprises a separate flexible loop body (typically fabric) that is attached in a releasable manner to the main body of a device, either by tying through a hole in the device body, attaching to the device body by a key ring, or releasably inserting a male connector portion into a compatible female connector portion. This establishes a detachable quality to the lanyard taught by Reinhold'823. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Granzotto'392 with the detachable lanyard as taught by Reinhold'823 to provide the Granzotto'392 system with the same advantage of releasably engaging the device around a user's neck and allowing for proper vertical

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adjustment of the electrodes to record an electrocardiographic complex (motivation to combine provided by Reinhold'823, column 5, lines 1-20).

17. Claim 14 is rejected under 35 U.S.C. 103(a) as obvious over Granzotto'392, or Granzotto'392 in view of Reinhold'823, or Granzotto'392 in view of Marangoni'783.

Regarding claim 14, Granzotto'392 discloses the invention substantially as claimed including that the push-down buttons must all be pushed down at the same time as explained above, but does not explicitly disclose that the period of time for which the push-down switches are maintained in a push-down state is at least 5 seconds. It would have been obvious to one having ordinary skill in the art at the time of the invention to hold the electrodes in the pushed down configuration for at least 5 seconds, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges (*In re Aller*, 105 USPQ 233) or optimum value of a result effective variable (*In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980)) involves only routine skill in the art.

Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Christopher A. Flory/
26 February 2009

/George Manuel/
Primary Examiner